K010883

APR - 6 2001

510(k) Summary
for
TERATECH Model 8EC4 Endocavity Smart Probe

1. SPONSOR

Teratech Corporation
77-79 Terrace Hall Road
Burlington, MA 01803

Contact Person: Charles F. Hottinger, Ph.D., RAC,
Regulatory Affairs Consultant

Telephone: 408-741-1006

Date Prepared: March 12, 2001

2. DEVICE NAME

Proprietary Name: TERATECH Model 8EC4 Endocavity Smart Probe
Common/Usual Name: Ultrasound Endocavity Transducer
Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

Acuson EC7 Endfire Endocavity Probe (K91805)

4. INTENDED USE

The TERATECH Model 8EC4 Endocavity Smart Probe is intended for endorectal and endovaginal (including fetal) imaging.

5. DEVICE DESCRIPTION

The TERATECH Model 8EC4 Endocavity Smart Probe is intended for use with the Model TERATECH 2000 , a portable ultrasound imaging system with grayscale or brightness (B-Mode) imaging. Technical specifications for the Model 8EC4 Endocavity Smart Probe with the Model 2000 are as follows:

System frequency: 5.0 MHz
Frame rate: 48-101 fps (imaging only)

Number of ultrasound lines per frame:	128
Fields of view:	2-10 cm
Radius of curvature of array:	10 mm
Element pitch:	0.2 mm
Elevational width:	5.0 mm
Elevational focus:	3.0 cm
Mode of Operation:	2D imaging
Image display:	Trapezoidal (147°)

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The TERATECH Model 8EC4 Endocavity Smart Probe is substantially equivalent to the Acuson EC7, which is currently in commercial distribution in the United States. The TERATECH Model 8EC4 Endocavity Smart Probe is identical in design and materials to the Acuson EC7; when operated with the TERATECH Model 2000 portable imaging system, the Model 8EC4 has intended uses and a mode of operation which are a subset of those of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2001

Teratech Corporation
C/O Mark Job, 510(k) Program Manager
TUV Product Service
1775 Old Highway 8 N.W.
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K010883
Trade Name: Teratech Model 8EC4 Endocavity Smart Probe
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: March 22, 2001
Received: March 23, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Teratech Model 2000 Portable Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Numbers:

8EC4

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to

895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Terason 2000_____
Transducer: _____Endocavity 8EC4

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Speci
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) Thyroid, Breast, Testes, etc.							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N						
	Trans-vaginal	N						
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: : P: uses previously cleared for the Model 2000 Imaging system under K992505 with 3 MHz Model L3 (Linear) Transducer .

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010883

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Terason 2000_____
Transducer: (see comments)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Speci
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal	P						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P						
	Small Organ (Specify) Thyroid, Breast, Testes, etc.							
	Neonatal Cephalic	P						
	Adult Cephalic	P						
	Trans-rectal	N						
	Trans-vaginal	N						
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P						
	Cardiac Pediatric	P						
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P						
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: P: uses previously cleared under K992505 with 3 MHz Model L3 (Linear) Transducer (including use in military field settings in addition to hospital/clinic settings): Models 4V2 (Phased) and 4C2 (Convex) Smart Probes added under Appendix E; N: subject of this submission for Model 8EC4 Endocavity Smart Probe.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K010883